UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

LOUIS BERTINI and DEBRA BERTINI,

Plaintiffs,

- against -

SMITH & NEPHEW, INC.,

Defendant.

MEMORANDUM DECISION AND ORDER

13 Civ. 79 (BMC)

COGAN, District Judge.

This is a diversity products liability action involving a hip replacement system manufactured by defendant. Defendant has moved to dismiss plaintiffs' second amended complaint on the grounds that federal law regulating these devices preempts plaintiffs' state law claims, and that beyond the preemption issue, the pleading is inadequate to state a claim.

In their initial complaints, plaintiffs attacked a particular part in the defendant's hip replacement system as defective. Recognizing that claims against this part are preempted, they now seek to attack the system itself. But this does not solve plaintiffs' problem, because a factfinder could not find that the system is defective without finding that the particular part is defective. Accordingly, defendant's motion to dismiss is granted.

BACKGROUND

I. History of Defendant's R3 Acetabular System

The hip is a ball and socket joint; the femoral head is the ball and the acetabulum is the socket. During total hip replacement surgery, the femoral head is removed and replaced with a

prosthetic ball. The acetabulum is removed and replaced with a prosthetic shell. The prosthetic femoral head attaches to the taper of a stem which is implanted in a patient's femur.

Smith & Nephew, Inc. ("Smith & Nephew")'s R3 Acetabular System ("R3 System") is a hip implant system used in total hip replacement procedures. The R3 System is made up of the Acetabular Cup (shell) ("R3 acetabular shell") and one of several possible liners. It is used in conjunction with Smith & Nephew's portfolio of hip stems and femoral heads. The liner's purpose is to prevent the loosening of the hip components, which is a defect in total hip replacement systems that often results in pain and a decrease in the hip implant's stability. The R3 locking mechanism is a feature of the R3 acetabular shell, designed to ensure that a liner remains secure within the R3 acetabular shell. Smith & Nephew received approval from the U.S. Food and Drug Administration (the "FDA") to market and sell the R3 System.[1]

Smith & Nephew later developed the Birmingham Hip Resurfacing (BHR) System ("BHR System"), an implant used in hip resurfacing surgery. In contrast with total hip replacement surgery, during hip resurfacing, the femoral head is trimmed and capped with a covering, rather than replaced. The BHR System was approved for sale through the pre-market approval ("PMA") process, which requires a device manufacturer to provide the FDA with "reasonable assurance" that its device is safe and effective. Medtronic, Inc. v. Lohr, 518 U.S. 470, 477, 116 S. Ct. 2240, 2243 (1996). The FDA granted Smith & Nephew supplemental PMA to sell its R3 acetabular metal hip liner ("R3 metal liner") specifically with the BHR System.

[1] Exhibit B to plaintiffs' September 18, 2013 letter indicates that the R3 System received § 510(k) approval on June 6, 2007. I take judicial notice of this document. See Fed. R. Evid. 201(b)(2) (noting that a court may take judicial notice of documents where they "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned"); see also Manley v. Utzinger, No. 10 CV 2210, 2011 WL 2947008, at *1 n.1 (S.D.N.Y. July 21, 2011) ("The Court may take judicial notice of public records in deciding a motion to dismiss").

II. Plaintiff's Operation

After being diagnosed with osteoarthritis, plaintiff Louis Bertini underwent total hip replacement surgery for his left hip on October 26, 2009. Mr. Bertini's surgeon implanted the R3 System with the R3 metal liner.

In 2011, Mr. Bertini began experiencing physical problems with his left hip, including popping and clicking sensations. Less than 16 months after Mr. Bertini's original hip replacement surgery, he was forced to undergo revision surgery. Mr. Bertini's surgeon discovered mechanical problems with Mr. Bertini's R3 System. Specifically, the surgeon "was able to easily remove the R3 metal liner from the R3 shell as it had loosened within the shell." Also, the "R3 System's locking mechanism . . . failed to hold the R3 metal liner in a secure and stable position, which allowed the R3 metal liner to become unsecure and loosen within the R3 shell . . . ." These failures caused Mr. Bertini "pain and mechanical symptoms."

On June 1, 2012, Smith & Nephew recalled all batches of R3 metal liners, including the type implanted in Mr. Bertini. Smith & Nephew explained that the recall was in response to a higher number of revision surgeries than expected, due in part to the premature loosening of the liner. Mr. Bertini claims that neither he nor his physicians would have used the R3 System had they known of the R3 System's "increased rate of failure." On August 14, 2013, Plaintiffs filed their second amended complaint against Smith & Nephew.

III. The Instant Motion

Defendant has moved to dismiss the amended complaint, arguing that plaintiffs' claims are preempted under the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c ("MDA") or, alternatively, that plaintiffs have failed to state any claims upon which relief could be granted.

DISCUSSION

I. Federal Preemption of State-Law Claims Under the MDA

The MDA established a system of federal oversight for the introduction of new medical devices. Devices are organized into three different classes, with Class III receiving the most federal oversight. See Riegel v. Medtronic, Inc., 552 U.S. 312, 317, 128 S. Ct. 999, 1003 (2008). A device is assigned to Class III if there are not any less stringent classifications which would reasonably assure the device's safety and effectiveness, and the device is "'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" Id. (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

New Class III devices must be approved through the PMA process. See Lohr, 518 U.S. at 477, 116 S. Ct. at 2246. However, if a device is "substantially equivalent" to a device which received FDA approval before the introduction of the MDA, it can avoid the PMA process and instead obtain approval through the § 510(k) process. 21 U.S.C. § 360c(f)(1)(A). Most Class III medical devices receive approval through the § 510(k) process. See Riegel, 552 U.S. at 317, 128 S. Ct. at 1004.

The MDA includes a preemption provision, 21 U.S.C. § 360k ("§ 360k"), which prevents any "State or political subdivision of a State" from establishing or continuing in effect any requirement, with respect to a device intended for human use, which "(1) is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k.

Since § 360k applies only to "state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law," a court must first "determine whether the Federal Government has established requirements applicable" to the device at issue. Riegel, 552 U.S. at 321, 128 S. Ct. at 1006 (quoting 21 U.S.C. § 360k(a)). The Supreme Court has held that the PMA process imposes federal "requirements" on medical device manufacturers, while the § 510(k) process does not. Id., 552 U.S. at 322, 128 S. Ct. at 1007. This can be explained by the differences in each of these approval processes. The § 510(k) approval process is solely focused on whether a device is equivalent to a previously-approved device. See id., 552 U.S. at 323, 128 S. Ct. at 1007. In fact, a device approved through § 510(k) may have "never been formally reviewed under the MDA for safety or efficacy." Id. (quoting Lohr, 518 U.S. at 493, 116 S. Ct. at 2254). In contrast, the PMA process' main objective is establishing that a device is safe and effective. See id.

If a medical device was approved through the PMA process, and therefore federal requirements were imposed on the manufacturer, then courts must determine whether a plaintiff's common law claims are based on state requirements that are "different from, or in addition to" the applicable requirements under federal law, and that relate to the device's safety and effectiveness. 21 U.S.C. § 360k. Generally, a state's "requirements" refers to its common law duties, which are based on the "existence of a legal duty" under that state's laws. Riegel, 552 U.S. at 324, 128 S. Ct. at 1008 (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 522, 112 S. Ct. 2608, 2620 (1992)). If a state common law, for instance, requires that a medical device manufacturer design a certain device in a manner that is safer than a model that the FDA has already approved, this could "disrupt the federal scheme." Id., 552 U.S. at 325, 128 S. Ct. at 1008. Under § 360k, if that manufacturer received approval to sell its device through the PMA

process, then a subsequent action against the manufacturer under that state's common law would be preempted. See Gelber v. Stryker Corp., 788 F. Supp. 2d 145, 153 (S.D.N.Y. 2011). On the other hand, if a cause of action under state common law only provides "a damages remedy for claims premised on a violation of FDA regulations," then the state duties "'parallel' rather than add to, federal requirements," and the cause of action is not preempted under § 360k. Riegel, 552 U.S. at 330, 128 S. Ct. at 1011. To avoid imposing state requirements on a device manufacturer which are in addition to or different from federal requirements, a plaintiff must establish that the state and federal requirements are equivalent. See McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005).

Finally, the mere failure to comply with FDA provisions does not automatically provide a private litigant with a cause of action; it is the federal government that is authorized to file suit for noncompliance with medical device provisions. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4, 121 S. Ct. 1012, 1018 (2001). A plaintiff is required to show specific violations of federal law, and then link those violations to his own injuries. See Gale v. Smith & Nephew, Inc., No. 12 CV 3614, 2013 WL 563403, at *4 (S.D.N.Y. Feb. 13, 2013).

II. Plaintiffs' Claims

The R3 System was approved via the § 510(k) process.[2] The R3 metal liner used with the R3 System was approved through the PMA process, but only for use with the BHR System. Plaintiffs' claims are largely based on the R3 metal liner's interaction with the R3 System, specifically the R3 acetabular shell and its locking mechanism. Preemption analysis is therefore complicated by the fact that claims involving the R3 metal liner are likely preempted, since the

[2] In defendant's August 29, 2013 letter, it contends that the R3 acetabular shell, a component of the R3 System, received supplemental PMA approval for use with the BHR System. However, defendant attached as Exhibit C to its letter a PMA Approval Order Statement acknowledging "Approval for the addition of an alternative site for the porous coating process for the r3 acetabular shells," not approval for the R3 acetabular shell itself.

liner received supplemental PMA approval, but claims solely alleging defects with the R3 System are unlikely to be preempted, since the R3 System was approved through the § 510(k) process. See Riegel, 552 U.S. at 322, 128 S. Ct. at 1007.

Many courts have addressed situations in strict liability actions against medical device manufacturers in which an individual component of a medical device was approved through the §510(k) process and then later incorporated into a medical device system approved for sale through the PMA process. In these cases, plaintiffs have argued that preemption analysis should only apply to the specific device components that originally received approval through the PMA process. See Duggan v. Medtronic, Inc., 840 F. Supp. 2d 466, 471 (D. Mass. 2012). Under this theory, the portion of a claim involving certain components should be preempted while the remainder of the claim should remain. Courts have rejected such arguments and instead have held that there should not be a separate preemption analysis for each component of a medical device. See id. ("Many courts have held that once premarket approval is granted [to a medical device], all claims relating to all components of the device are preempted."); Caccia v. Biomet, Inc., 13 CV 73, 2013 WL 4502211, at *5 (N.D. Ind. Aug. 21, 2013) (dismissing "[the] argument that the law affords different preemption status to individual parts of a total system . . . ."); Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010) ("[A]ttempting to separate the component parts of a medical device for purposes of preemption is not appropriate."). In reaching this conclusion, courts have focused on the fact that it would not make sense, and in some instances, it would be "impossible" to separate different components of a device and apply different preemption analyses to each. Riley v. Cordis Corp., 625 F.Supp.2d 769, 780 (D.Minn.2009). Further, distinguishing between different components within a single system

would "add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers." Lewkut, 724 F. Supp. 2d at 656.

In the present case, the factual situation differs slightly from the above cited cases. Rather than a PMA-approved system incorporating a § 510(k)-approved component, Mr. Bertini was implanted with a hip replacement system which received § 510(k) approval, but utilized a PMA-approved R3 metal liner. Nonetheless, as in the above-cited cases, preemption analysis should focus on the hip replacement device implanted in Mr. Bertini as a whole, rather than individual components within that device.

While the R3 metal liner is just one part of the hip replacement system, it is the main focus of plaintiffs' Complaint. Plaintiffs attribute Mr. Bertini's injuries to two separate but interrelated defects: "the loosening of the R3 metal liner and the failure of the locking mechanism in the R3 System to hold the R3 metal liner in place." The liner's purpose is to prevent the other hip components, including the R3 acetabular shell and its locking mechanism, from loosening. Similarly, the locking mechanism feature is supposed to ensure that the liner stays connected to the R3 acetabular shell; essentially, it assists the liner in performing the liner's function. Although plaintiffs describe these device failures as two separate defects, they are in large part describing the same phenomena – the R3 metal liner's inability to attach to the R3 acetabular shell, which resulted in plaintiffs' injuries.

Because plaintiff's injuries are alleged to have been caused by the failure of multiple components, I must apply a preemption analysis for the hip replacement system as one unit, and not examine each individual component. See Lewkut, 724 F. Supp. 2d at 656; Riley, 625 F. Supp. 2d at 780. Assuming that I did apply a preemption analysis to each individual component, I would find that plaintiff's claims with respect to the R3 metal liner, which received PMA

approval, would be preempted, whereas the claims related to the R3 System, including the R3 acetabular shell and locking mechanism, would not be preempted. See Riegel, 552 U.S. at 322-323, 128 S. Ct. at 1007. But, left solely with their claims with respect to the R3 System, plaintiffs would be unable to show that the R3 acetabular shell and its locking mechanism alone proximately caused plaintiffs' injuries, because plaintiffs have plead that the R3 System *and* the R3 metal liner together were the cause of plaintiff's injuries. Plaintiffs would have to prove that the R3 acetabular shell did not stay attached to the R3 metal liner, without being able to argue, as they have repeatedly throughout this litigation, that this failure to attach was due in large part to the R3 metal liner improperly loosening from the R3 acetabular shell. Therefore, if a claim involving the R3 metal liner's alleged defect is preempted, the entire claim should be dismissed because plaintiffs will be unable to sufficiently plead the remainder of that claim.

1. *Strict Liability – Design Defect*

In order to plead a claim for defective design, a plaintiff must show that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001).

Plaintiffs argue that both the R3 System and the R3 metal liner, as designed, were defective and unreasonably dangerous, and that their designs led to an increased rate of failure requiring revision surgery. According to plaintiffs, it was feasible for defendant to design the R3 System and R3 metal liner in a safer manner. The amended complaint points to other medical device manufacturers who were able to design similar devices with a lower failure rate. These design defects were allegedly a substantial cause of plaintiffs' injuries.

As mentioned above, an action based on state law that would require a manufacturer to design a device, which has already received PMA approval, in a manner that is safer than what the FDA requires would impose additional state safety requirements on the device, and therefore this claim would be preempted under § 360k. See Riegel, 552 U.S. at 325, 128 S. Ct. at 1008. There is little doubt that a claim for strict liability under the theory of design defect relates to the safety and effectiveness of a medical device. See Colon, 199 F. Supp. 2d at 83-84.

Since the FDA, through the PMA process, allowed Smith & Nephew to sell the R3 metal liner component with the BHR System, it indicated that it was satisfied that the R3 metal liner was reasonably safe and effective. Plaintiffs are not claiming that defendant failed to meet the FDA's requirements. Rather, the design defect claim rests on the alleged ability of Smith & Nephew to design an even safer device component. Therefore, this cause of action would impose additional requirements on defendant to design an even safer device component. Since these additional state requirements relate to the safety and effectiveness of defendant's devices, the portion of the design defect claim based on the R3 metal liner is preempted under the MDA. See Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206, 1222 (W.D. Okla. 2013) ("To permit a jury to second-guess the [device's] design would risk interference with the federally-approved design standards and criteria"); Simon v. Smith & Nephew, Inc., No. 13 CV 1909, 2013 WL 6244525, at *7 (S.D.N.Y. Dec. 3, 2013) ("[D]esign defect claims regarding a PMA-approved device are squarely preempted by the MDA").

Plaintiffs stress that although the R3 metal liner was approved through the PMA process, it was only approved for use with the BHR System, but defendant nonetheless marketed the R3 metal liner to be used with the R3 System. However, preemption analysis is not concerned with how a particular device is used or whether there are federal requirements imposed on a particular

use of the device. Rather, preemption is focused on whether there are federal requirements applicable to the device itself. See Riley, 625 F. Supp. 2d at 779. Indeed, "'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate . . . without directly interfering with the practice of medicine." Buckman Co., 531 U.S. at 350, 121 S. Ct. at 1018; see also United States v. Caronia, 703 F.3d 149, 153 (2d Cir. 2012) ("Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs."). That the R3 metal liner was approved for use with the BHR System does not affect defendant's preemption argument under the MDA, since the specific component at issue received PMA.

The R3 locking mechanism, as a feature of the R3 System, was approved through the § 510(k) process. Because the § 510(k) process does not apply federal safety requirements to the device, and because no other federal safety requirements have been identified by plaintiffs as being applicable to the R3 System, the design defect claim is not preempted. See Riegel, 552 U.S. at 322-323, 128 S. Ct. at 1007. However, plaintiffs have not pled facts showing that the R3 locking mechanism's alleged design defect alone substantially caused their injuries. Plaintiffs claim that the R3 locking mechanism was defective because it "did not secure the R3 metal liner to the R3 shell, causing the R3 metal liner to prematurely loosen within the R3 shell and loosen from other total hip replacement components." Since plaintiffs' position is that their injuries were caused by the locking mechanism and the R3 metal liner's inability to stay attached to one another, their injuries were caused not just by the R3 acetabular shell and its locking mechanism, but also by the R3 metal liner's inability to connect to the R3 acetabular shell. For this reason,

plaintiffs' entire design defect claim is dismissed as preempted under the MDA. See Lewkut, 724 F. Supp. 2d at 656; Riley, 625 F.Supp.2d at 780.

2. *Strict Liability – Failure to Warn*

Under New York law, a medical device manufacturer has a duty "to warn of all potential dangers which it knows or should know, and must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession." Figueroa v. Boston Scientific Corp., 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003) (quoting Glucksman v. Halsey Drug Co., Inc., 160 A.D.2d 305, 307, 553 N.Y.S.2d 724, 726 (1990)). To bring a claim against a manufacturer for failure to warn, "a plaintiff must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers . . . was a proximate cause of his or her injuries." Id., 254 F. Supp. 2d at 369-70 (quotations and citations omitted).

Plaintiffs claim that Smith & Nephew "misrepresented and failed to adequately warn health care professionals and the public . . . that the R3 System was defective because the R3 metal liner did not properly sit and adhere to the R3 shell leading to an increased risk of prematurely loosening and failing, and subjecting patients to revision surgery at an unacceptable rate." Plaintiffs also claim that defendant failed to timely and reasonably warn that the "R3 System's locking mechanism failed to properly secure a R3 metal liner in an R3 shell . . . ." According to plaintiffs, had defendant adequately warned the public and health care professionals about the R3 System and R3 metal liner's defects, Mr. Bertini's physicians would not have used those devices.

Plaintiffs cite several FDA regulations which defendant allegedly violated. These regulations require, among other things, that medical device manufacturers have systems in place to maintain quality control; investigate non-conforming devices; and investigate all complaints

about medical devices, and in some instances, report such complaints to the FDA. Notably, none of these federal regulations require that defendant notify the public and physicians directly when it learns that its device is not performing adequately.

Because plaintiffs fail to identify a federal requirement that defendant warn the public and health care professionals directly that its devices were defective, plaintiffs' "failure to warn" theory of strict liability does not "parallel" federal requirements. But cf. Riegel, 552 U.S. at 330, 128 S. Ct. at 1011 ("§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements") (citations omitted). See also Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 281 (E.D.N.Y. 2009) ("[S]imply alleging that the defendants violated federal regulations did not necessarily mean that the plaintiff's strict liability claim was premised on those violations."). Instead, allowing plaintiffs' failure to warn claim to proceed would impose requirements on defendant that demand that it go further than what federal regulations require.

Plaintiffs also argue that defendant did not adequately warn health care professionals and the public about the R3 locking mechanism's defect, because it failed to note that the locking mechanism did not properly secure a R3 metal liner to the R3 shell. As noted above, there should not be different preemption analyses for separate device components that operate as a single unit. See Lewkut, 724 F. Supp. 2d at 656. That is particularly true here, where the separate components' alleged defects are interconnected and are claimed to have caused a single failure within the hip replacement system. This interaction between the R3 metal liner and the R3 locking mechanism makes it impossible for plaintiffs to plead sufficient facts showing that

the R3 locking mechanism, on its own, caused their injuries. Therefore, under § 360k, plaintiffs' entire failure to warn claim is dismissed as preempted under the MDA.

3. *Strict Liability – Manufacturing Defect*

"To plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." Colon, 199 F. Supp. 2d at 85 (quoting Caprara v. Chrysler Corp., 52 N.Y.2d 114, 129, 436 N.Y.S.2d 251, 258 (1981)). "In other words, a manufacturing flaw exists when the unit in question deviates in quality and other performance standards from all of the other identical units." Id. A manufacturing defect claim should be dismissed if plaintiff has not alleged that "the particular [product] administered to her had a defect compared to other samples of that [product]." Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012) (quotation marks and citations omitted).

In support of their manufacturing defect claim, plaintiffs argue that defendant designed, manufactured, marketed, and sold the R3 System with the R3 metal liner and that the R3 System "was defective and unreasonably dangerous in manufacture when it entered the stream of commerce and was received by Plaintiff Louis Bertini." Specifically, the R3 System was defective because of the R3 metal liner's "inability to properly sit and adhere to the R3 shell" and the R3 locking mechanism's failure to secure the R3 metal liner to the R3 acetabular shell. According to plaintiffs, these manufacturing defects "led to an increased risk for failure requiring revision surgery that is unreasonably greater than other similar products, and a revision rate that was more than two to three times what medical authorities consider an average revision rate at four years." The defects were a "substantial cause of Plaintiffs' injuries."

Plaintiffs have failed to plead facts showing that that the specific device implanted in Mr. Bertini "deviate[d] in quality and other performance standards" from the other R3 Systems and R3 metal liners that defendant marketed and sold. Colon, 199 F. Supp. 2d at 85. Instead, plaintiffs allege that the R3 System and R3 metal liner were defectively designed. For example, in claiming that there was a manufacturing defect, plaintiffs argue that the revision rate for users of the R3 System and R3 metal liner was much higher than average. If proven, this shows that the R3 metal liner and R3 System, as designed, were defective, but not that the specific components implanted in Mr. Bertini suffered from a manufacturing defect. Further, the second amended complaint does not attribute the R3 System and R3 metal liner's failure to a specific portion of the defendant's manufacturing process that went awry.

Finally, plaintiffs attempt to support their manufacturing defect claim by arguing that defendant manufactured, marketed, and sold the R3 System with the R3 metal liner despite the fact that the liner was approved for use with the BHR System. However, off-label usage of a medical device component is a widely accepted practice. See Buckman Co., 531 U.S. at 350, 121 S. Ct. at 1018. Regardless, the off-label use of a device component does not show that the unit implanted in Mr. Bertini was defective compared with all other units sold by defendant. Because plaintiffs failed to plead that the specific unit implanted in Mr. Bertini was defective, plaintiffs' third cause of action is dismissed.

4. *Negligence*

"To make out a prima facie case for negligence in New York, a plaintiff must show (1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, i.e. reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff's injury; and (4) loss or

damage." Colon, 199 F. Supp. 2d at 82. "New York courts generally consider strict products liability and negligence claims to be functionally synonymous." Pinello v. Andreas Stihl Ag & Co. KG, No. 08 CV 00452, 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011) (quotations and citations omitted).

Plaintiffs' negligence claim is in large part the same as their strict products liability claim, since both are based on the R3 System and R3 metal liner's alleged defective design. Plaintiffs argue that defendant was negligent because it knew or should have known that its devices had an increased risk of failure due to their defective design, yet continued to market, distribute and sell these devices anyway. According to plaintiffs, had defendant "performed adequate dynamic testing of the R3 System and R3 metal liner," it would have noticed the design and manufacturing defects and kept those devices off the market. In turn, plaintiffs' injuries would have been avoided.

For the same reasons that plaintiffs' design defect claim is dismissed as preempted, plaintiffs' negligence claim is also dismissed. The FDA approved the R3 metal liner's design when, through the PMA process, it allowed defendant to market and sell the R3 metal liner. Plaintiffs, in arguing that defendant was negligent for not noticing that its design was defective, are attempting to hold defendant liable for not designing the R3 metal liner in a manner safer than what the FDA requires. This negligence cause of action would impose additional safety requirements on defendant's device beyond what is required by federal regulations. Therefore, this claim is dismissed as preempted. See Horowitz, 613 F. Supp. 2d at 280 ("What is clear after Riegel is that claims which impose 'liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted'") (citations omitted). Further, for the same

reason that plaintiffs' design defect claim was dismissed in its entirety – because plaintiffs have not pled that only the R3 System and its locking mechanism were the cause of plaintiffs' injuries – plaintiffs' negligence claim is also dismissed in its entirety.

5. *Fraudulent Misrepresentation and Omission*

"The elements of fraud under New York law are: '[1] a misrepresentation or a material omission of fact which was false and known to be false by defendant, [2] made for the purpose of inducing the other party to rely upon it, [3] justifiable reliance of the other party on the misrepresentation or material omission, and [4] injury.'" Premium Mortgage Corp. v. Equifax, Inc., 583 F.3d 103, 108 (2d Cir. 2009) (citations omitted).

Plaintiffs claim that "[d]efendant fraudulently misrepresented, including in the Company's February 27, 2009 Press Release . . . that the R3 metal liner was approved for use in the United States with the R3 System." Plaintiffs also allege that defendant "fraudulently failed to disclose that the R3 System was not approved for use in the United States with the R3 System." Defendant's conduct "risked the lives and health of consumers and users of their products, including Plaintiff Louis Bertini" and defendant "made conscious decisions not to redesign, re-manufacture, re-label, warn or inform the unsuspecting public that the R3 metal liner was not approved for use with the R3 System."

According to plaintiffs, "[Mr.] Bertini and the medical community justifiably relied on Defendant's representations and omissions by purchasing and using the R3 System with the R3 metal liner." However, the mere fact that Mr. Bertini purchased the R3 System with the R3 metal liner does not show that the Mr. Bertini or his physician actually relied on defendant's alleged misrepresentations and omissions when deciding whether to proceed with Mr. Bertini's surgery. See Pacs Indus., Inc. v. Cutler-Hammer, Inc., 103 F. Supp. 2d 570, 572 (E.D.N.Y.

2000) (dismissing claim of fraud where only reliance shown was purchase of defendant's product). Further, while plaintiffs note that defendant issued its press release before Mr. Bertini's initial hip replacement surgery, the second amended complaint contains no allegation that Mr. Bertini, or even Mr. Bertini's physician, read defendant's press release. Nor does the complaint allege that they relied on the press release's alleged misrepresentations when deciding whether to implant the R3 metal liner in Mr. Bertini. Without pleading reliance, plaintiffs' fraudulent misrepresentation and omission claim cannot stand. See Premium Mortgage Corp., 583 F.3d at 108; Vermeer Owners, Inc. v. Guterman, 78 N.Y.2d 1114, 1116, 578 N.Y.S.2d 128, 129-30 (1991) (affirming dismissal of fraud claim, noting that "[n]othing in this record establishes that plaintiffs in fact relied on any misrepresentation by defendants to their detriment."). Because plaintiffs have not shown reliance, plaintiffs' argument that the press release constituted an "off-label" promotion is irrelevant.

Additionally, Federal Rule of Civil Procedure 9(b) provides that "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A plaintiff bringing a fraud claim must allege "the time, place, speaker, and sometimes even the content of the alleged misrepresentation." Bangkok Crafts Corp. v. Capitolo Di San Pietro in Vaticano, 03 CV 0015, 2006 WL 1997628, at *5 (S.D.N.Y. July 18, 2006) (quoting Ouaknine v. MacFarlane, 897 F.2d 75, 79 (2d Cir. 1990)). Although plaintiffs allude to other misrepresentations and omissions, the only one identified with the degree of particularity required by Fed. R. Civ. P. 9(b) is the press release. As noted above, plaintiffs have failed to allege any reliance on the press release. Accordingly, plaintiffs' fraudulent misrepresentation and omission claim is dismissed in its entirety.

6. *Breach of Implied Warranty*

In order to successfully plead a breach of implied warranty claim, a plaintiff "must show that the product was not reasonably fit for its intended purpose, an inquiry that focuses on the expectations for the performance of the product when used in the customary, usual[,] and reasonably foreseeable manners." Porrazzo v. Bumble Bee Foods, LLC, 822 F. Supp. 2d 406, 420-21 (S.D.N.Y. 2011) (citation omitted).

Plaintiffs allege that "[t]he R3 System, including the R3 metal liner, was not reasonably fit for the ordinary purpose for which it was used and did not meet the expectations for the performance as expected being used in a reasonably foreseeable manner, nor was it minimally safe for its foreseeable purposes." Plaintiffs further allege that the breach of warranty was a substantial factor in causing Mr. Bertini's injuries. The portion of plaintiffs' claim addressing the R3 metal liner is preempted under the MDA. See Horowitz, 613 F. Supp. 2d at 284. This is because the FDA approved the R3 metal liner's design for safety and effectiveness when it allowed defendant to sell the liner after the liner went through the supplemental PMA process. Plaintiffs must show defendant's product "was not minimally safe for its expected purpose" to maintain their breach of implied warranty claim. Caronia v. Philip Morris USA, Inc., 715 F.3d 417, 434 (2d Cir. 2013) (quoting Denny v. Ford Motor Co., 87 N.Y.2d 248, 259, 662 N.E.2d 730, 736 (1995)). Under the MDA, plaintiffs cannot demand that defendant design the R3 metal liner in a safer manner, when the FDA has already approved the safety and effectiveness of defendant's design. See Horowitz, 613 F. Supp. 2d at 284 (Breach of implied warranty claim "falls squarely within the MDA's preemption provision.").

Further, plaintiffs have not pled specific facts in support of their breach of implied warranty claim showing that the R3 System and R3 metal liner were not reasonably fit for their

ordinary purposes. Instead, plaintiffs simply state that "[t]he R3 System, including the R3 metal liner, was not reasonably fit for the ordinary purpose for which it was used and did not meet the expectations for the performance as expected being used in a reasonably foreseeable manner, nor was it minimally safe for its foreseeable purposes." This allegation is conclusory and "not entitled to an assumption of truth." See Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950 (2009).

Finally, plaintiffs have not alleged that defendant's breach of implied warranty was due to a failure to comply with FDA requirements. See Bass v. Stryker Corp., 669 F.3d 501, 517 (5th Cir. 2012) (finding that post-Riegel cases dismissing breach of implied warranty claims as preempted "concluded that the claims failed to rely on violations of the FDA's requirements"). Without identifying any FDA regulations that defendant has allegedly violated, plaintiffs' breach of implied warranty claim is preempted. See In re Bayer Corp. Combination Aspirin Products Mktg. & Sales Practices Litig., 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010) (quoting Riley, 625 F. Supp. 2d at 777) ("For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA."). Therefore, plaintiffs' cause of action for breach of implied warranty is dismissed.

7. *Loss of Consortium*

"A claim for loss of consortium or services is a derivative action, and in the common law of New York, does not exist 'independent of the injured spouse's right to maintain an action for injuries sustained.'" Jordan v. Lipsig, Sullivan, Mollen & Liapakis, P.C., 689 F. Supp. 192, 196 (S.D.N.Y. 1988) (quoting Liff v. Schildkrout, 49 N.Y.2d 622, 632, 427 N.Y.S.2d 746, 749

(1980)). Since Mr. Bertini's claims are dismissed, Ms. Bertini's derivative claim cannot proceed. See Jordan, 689 F. Supp. at 196.

CONCLUSION

For the reasons stated above, defendant's motion to dismiss is granted in its entirety.

SO ORDERED.

/s/ Brian M. Cogan

U.S.D.J.

Dated: Brooklyn, New York
March 14, 2014